SUPPORT FOR AMENDMENTS

Claims 2, 4, 5, and 17-18 are canceled without prejudice to their continued prosecution in a continuation and/or divisional application.

The amendments to the specification and to claims 19, 20, and 21 were made solely to correct typographical errors.

The amendments to independent claims 1, 15, and 23 are fully supported by canceled claims 2, 4, 5, and 17-18 and by the description in the specification (e.g., page 5, lines 1-2, 13-16 and 29-30; page 9, lines 16-30; etc.).

No new matter has been added. Upon entry of this Response, claims 1, 3, 6-15, and 19-25 are present and active in the application with claims 7-8, 12, and 20-22 presently withdrawn as being drawn to non-elected specie.

REMARKS

Claim Objections

The objection to claim 19 for containing an informality has been obviated. Accordingly, withdrawal of this ground of objection is respectfully requested.

Claim Rejections – 35 U.S.C. § 102

1. The rejection of claims 2, 4, and 17 under 35 U.S.C. § 102(b) as being anticipated by *Tomer et al.* (*Blood*, **1988**, *71*, No. 5, 1244-1252) in light of *Jing et al.* (*Chinese Medical Journal*, **2002**, *115*, No. 7, 983-986) and *Houwen et al.* (U.S. Patent No. 5,830,701) has been rendered moot by the cancellation of these claims. Accordingly, withdrawal of this ground of rejection is respectfully requested.

2. The rejection of claims 1, 3, 6, 10-11, 13-16, 19, and 23-25 under 35 U.S.C. § 102(b) as being anticipated by *Tomer et al.* in light of *Jing et al.* and *Houwen et al.* has been obviated.

As presently written, each of independent claims 1, 15, and 23 recites a preparation of an assay sample in which "the preparing does not involve an immunological method" (emphasis added). In direct contrast, the primary reference *Tomer et al.* describes flow cytometric analysis of normal human megakaryocytes in which the megakaryocytes are labeled by immunological methods—specifically, using fluoresceinated IgG_1 mouse monoclonal antibodies (or $F(ab')_2$ fragments thereof) directed to a platelet-specific GPIIb/IIIa epitope (e.g., page 1245, column 1, second full paragraph; etc.). Thus, for at least this reason, Applicants respectfully submit that the claimed invention is neither anticipated by nor would have been obvious in view of *Tomer et al.*

Moreover, secondary reference *Jing et al.* (cited merely as extrinsic evidence of inherency under MPEP 2131.01) also describes sample preparations based on immunological methods (e.g., page 984, column 1, first full paragraph; etc.). Accordingly, for at least this reason, Applicants respectfully submit that the claimed invention is likewise neither anticipated by nor would have been obvious in view of *Jing et al.*

Finally, secondary reference *Houwen et al.* (cited in this ground of rejection merely as extrinsic evidence under MPEP 2131.01) neither anticipates nor would have rendered obvious the claimed invention for at least the reasons explained in section 4 below.

For at least the reasons set forth above, Applicants respectfully submit that the claimed invention is neither anticipated by nor would have been obvious in view of *Tomer et al.* in light of *Jing et al.* and *Houwen et al.* Accordingly, withdrawal of this ground of rejection is respectfully requested.

3. The rejection of claims 2 and 5 under 35 U.S.C. § 102(b) as being anticipated by *Houwen et al.* has been rendered moot by the cancellation of these claims. Accordingly, withdrawal of this ground of rejection is respectfully requested.

4. The rejection of claims 1, 3, and 9-10 under 35 U.S.C. § 102(b) as being anticipated by *Houwen et al.* has been obviated.

As presently written, independent claim 1 recites "preparing an assay sample by combining a sample comprising a cell with a reagent comprising a fluorescent dye" (emphasis added). *Houwen et al.* describes a method of detecting hematopoietic progenitor cells in which a blood sample is mixed with a reagent capable of detecting immature cells (e.g., abstract, lines 3-4). The reagent described in *Houwen et al.* can be a water-soluble surfactant (e.g., col. 4, line 59 to col. 5, line 12), a solubilizing agent (e.g., col. 5, lines 29-64), an amino acid (e.g., col. 6, lines 14-23), a buffer agent (e.g., col. 6, lines 24-28) or an osmolarity modifier (e.g., col. 6, lines 29-31). However, in contrast to the claimed invention, *Houwen et al.* contains no teaching or suggestion of "combining a sample comprising a cell with a reagent comprising a fluorescent dye," as required by independent claim 1.

For at least the reasons set forth above, Applicants respectfully submit that the claimed invention is neither anticipated by nor would have been obvious in view of *Houwen et al.* Accordingly, withdrawal of this ground of rejection is respectfully requested.

Claim Rejections – 35 U.S.C. § 103

1. The rejection of claim 18 under 35 U.S.C. § 103(a) as being unpatentable over *Sakata* (*Sysmex Journal International*, **2000**, *10*, No. 1, 41-46) in view of *Houwen et al.*, *Walters et al.* (*Laboratory Hematology*, **2000**, *6*, 83-92), and *Ota et al.* (*Haematologia*, **2000**, *30*, No. 1, 11-21) has been rendered moot by the cancellation of this claim. Accordingly, withdrawal of this ground of rejection is respectfully requested.

2. The rejection of claims 15-16, 23, and 25 under 35 U.S.C. § 103(a) as being unpatentable over *Sakata* in view of *Houwen et al.*, *Walters et al.*, and *Ota et al.* has been obviated.

As presently written, each of independent claims 15 and 23 recites "generating a scattergram... using settings adjusted to display a megakaryocyte population" and "detecting [a] megakaryocyte if a population exists in a predetermined megakaryocyte region of the scattergram" (emphases added). As further explained below, these recitations are neither taught nor suggested by *Sakata*, *Houwen et al.*, *Walters et al.*, and *Ota et al.*, individually or in combination.

Sakata describes a measurement reagent for nucleated red blood cells that contains a polymethine dye. As acknowledged in the Office Action (page 9), *Sakata* is completely silent with respect to detection of megakaryocytes. Thus, not surprisingly, *Sakata* contains no teaching or suggestion of "generating a scattergram...using settings adjusted to display a megakaryocyte population," as required by each of independent claims 15 and 23 or of "detecting [a] megakaryocyte if a population exists in a predetermined megakaryocyte region of the scattergram," as further required by each of independent claims 15 and 23.

As noted above, *Houwen et al.* describes a method of detecting hematopoietic progenitor cells. However, *Houwen et al.* contains no teaching or suggestion of "generating a scattergram...using settings adjusted to display a megakaryocyte population," as required by each of independent claims 15 and 23 or of "detecting [a] megakaryocyte if a population exists in a predetermined megakaryocyte region of the scattergram," as further required by each of independent claims 15 and 23.

Walters et al. describes a performance evaluation of the Sysmex XE-2100 hematology analyzer. However, *Walters et al.* is completely silent with respect to detection of megakaryocytes. Thus, not surprisingly, *Walters et al.* contains no teaching or suggestion of "generating a scattergram...using settings adjusted to display a megakaryocyte population," as required by each of independent claims 15 and 23 or of "detecting [a] megakaryocyte if a population exists in a predetermined megakaryocyte region of the scattergram," as further required by each of independent claims 15 and 23.

Ota et al. describes a violet polymethine dye for staining megakaryocytes. However, *Ota et al.* contains no teaching or suggestion of "generating a scattergram...using settings adjusted to display a megakaryocyte population," as required by each of independent claims 15 and 23 or of "detecting [a] megakaryocyte if a population exists in a predetermined megakaryocyte region of the scattergram," as further required by each of independent claims 15 and 23.

Inasmuch as *Sakata*, *Houwen et al.*, *Walters et al.*, and *Ota et al.* fail to teach or suggest "generating a scattergram...using settings adjusted to display a megakaryocyte population," as required by each of independent claims 15 and 23 and "detecting [a] megakaryocyte if a population exists in a predetermined megakaryocyte region of the scattergram," as further required by each of independent claims 15 and 23, Applicants respectfully submit that the claimed invention is neither anticipated by nor would have been obvious in view of these references, individually or in combination, Accordingly, withdrawal of this ground of rejection is respectfully requested.

Double Patenting

1. The rejection of claims 2 and 5 on the ground of nonstatutory obviousness-type double patenting over claims 1, 4, and 8-12 of U.S. Patent No. RE 39,006 E in view of *Tomer et al.* has been rendered moot by the cancellation of these claims. Accordingly, withdrawal of this ground of rejection is respectfully requested.

2. The rejection of claims 1, 3, 9, and 10 on the ground of nonstatutory obviousness-type double patenting over claims 1, 4, and 8-12 of U.S. Patent No. RE 39,006 E in view of *Tomer et al.* has been obviated.

As presently written, independent claim 1 recites "preparing an assay sample by combining a sample comprising a cell with a reagent comprising a fluorescent dye" (emphasis added). By contrast, U.S. Patent No. RE 39,006 E (a reissue of the *Houwen et al.* reference already discussed above) contains no teaching or suggestion of "combining a sample comprising a cell with a reagent comprising a fluorescent dye," as required by independent claim 1.

Moreover, Applicants respectfully submit that the teachings of U.S. Patent No. RE 39,006 E are incompatible with the teachings of *Tomer et al.* inasmuch as these two references describe sample preparation methods based on completely different principles. By way of example, U.S. Patent No. RE 39,006 E describes a procedure in which a blood sample is mixed with a reagent without employing any immunological techniques (e.g., abstract, lines 3-5). By contrast, as noted above, *Tomer et al.* describes a procedure in which megakaryocytes are labeled by immunological methods. In accordance with MPEP 2143.01, if a "proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984)."

For at least the reasons set forth above, Applicants respectfully submit that the claimed invention would not have been obvious over claims 1, 4, and 8-12 of U.S. Patent No. RE 39,006 E in view of *Tomer et al.* Accordingly, withdrawal of this ground of rejection is respectfully requested.

Conclusion

In view of the Amendment and Remarks set forth above, Applicants respectfully submit that the claimed invention is in condition for allowance. Early notification to such effect is earnestly solicited.

If for any reason the Examiner feels that the above Amendment and Remarks do not put the claims in condition to be allowed, and that a discussion would be helpful to advance prosecution, it is respectfully requested that the Examiner contact the undersigned agent directly at (312)-321-4257.

Respectfully submitted,

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